

XVI International AIDS Conference, Toronto: August 13-18, 2006: Trip Report

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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CONTEXT

Acronyms	v
Background	1
Purpose of Trip	1
Scope of Work	1
Activities	3
Next Steps	7
Recommendations	7
Annex 1. Poster on Analyzing Medication Adherence Tools in Predicting ART Outcomes in Resource-Limited Settings.....	9
Annex 2. MSH RPM Plus experiences in procurement and supply management of AIDS Commodities	11
Annex 3. Improving the availability of ARVs in Namibia by streamlining the drug registration process.....	17
Annex 4. Toronto presentations	25
Annex 5. MSH Staffs group report on the AIDS 2006 Conference	27

ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
AMDS	AIDS Medicines and Diagnostics Services
ART	Antiretroviral Therapy
ARV	Antiretroviral medicines
GNP+	Global Network of People Living with HIV/AIDS
HAART	Highly Active Antiretroviral Therapy
IAS	International AIDS Society
ICASO	International Council of AIDS Service Organizations
IDPIG	International Drug Price Indicator Guide
ITT	Inventory Tracking Tool
MASRI	Medication Adherence Self-Report Inventory
MSH	Management Sciences for Health
PMTCT	Preventing Mother to Child Transmission
RPM Plus	Rational Pharmaceutical Management Plus
SCMS	Supply Chain Management System
TAG	Treatment Action Group
TRIPS	Trade Related aspects of Intellectual Property rights
UNAIDS	United Nations Programme on HIV/AIDS
VAS	Visual Analogue Scale
WHO	World Health Organization

BACKGROUND

The XVI International AIDS conference (AIDS 2006) was organized by the International AIDS Society (IAS) in collaboration with the co-organizers; the Global Network of People Living with HIV/AIDS (GNP+), the International Community of Women Living with HIV/AIDS, the International Council of AIDS Service Organizations (ICASO), the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the Canadian AIDS Society. The conference was held in Toronto, Canada from August 13-18, 2006. The IAS organized biennial conference is the world's premier event in the struggle against HIV/AIDS. The theme for the AIDS 2006 conference- "Time to deliver" was to reflect the continued urgency in bringing effective HIV prevention, care and treatment to communities, the demands for increased accountability and to commit to delivering this target.

The AIDS 2006 conference marked twenty-five years since the first report of AIDS appeared and ten years since the arrival of the Highly Active Antiretroviral Therapy (HAART). The conference provides an opportunity to share ideas on scientific and programmatic issues including strategies for the deployment of tools already available for the prevention, care and treatment of HIV/AIDS. MSH/RPM Plus participation at the AIDS 2006 provided an opportunity for sharing field experiences in the strengthening of health systems in developing countries to ensure availability and rational use of antiretroviral and related medicines. It also provides opportunities for the presentation of some MSH/RPM Plus oral presentation and posters, the delivery of skills building workshop and to attend sessions relevant to the work we are doing and for networking.

Purpose of Trip

Jude Nwokike, Senior Program Associate, traveled to the XVI International AIDS Conference held in Toronto, Canada from August 13-18, 2006, to make presentations and attend sessions of the Conference.

Scope of Work

1. Make a poster presentation on "Analyzing medication adherence measurement tools in predicting ART outcomes in resource-limited settings"
2. Make a presentation on "MSH RPM Plus experiences and tools for procurement and supply management of AIDS Commodities" during the WHO organized AMDS Satellite of the International AIDS Conference
3. Make a presentation on "MSH RPM Plus experiences in procurement and supply management of AIDS Commodities" at the WHO organized Skills building workshop
4. Distribute RPM Plus Tools Flyers during the Conference
5. Make an oral presentation on "Improving the availability of ARVs in Namibia by streamlining the drug registration process"
6. Attend relevant Skills building sessions of the Conference

7. Attend relevant plenary and sessions of the Conference
8. Liaise with other MSH attendees during the Conference

ACTIVITIES

Make a poster presentation on “Analyzing medication adherence measurement tools in predicting ART outcomes in resource-limited settings”

RPM Plus abstract on “Analyzing medication adherence measurement tools in predicting ART outcomes in resource-limited settings” was accepted for poster presentation at the XVI International AIDS conference. The poster (TUPE0129) was mounted from 10:15 - 18:30 on Tuesday, August 15th at the poster exhibition stand. The stand witnessed about 50 visitors who reviewed the work, made comments and discussed the work they are doing in the area of ART adherence. Some of the key questions and comments from visitors to the stand included:

- Standardization of the Visual Analogue Scale (VAS) is an issue and needs addressing
- The Algorithm in the abstract is wonderful. Viral Load should be included in it and it should start with VAS as the first step since it is an easy tool to use
- AXIOS has a Pharmacy refill system to trigger defaulter tracing in Nigeria
- What does % reliability refer to?
- There is adherence mobile technology tools being developed including the “HAART Phones”
- University of Edmonton has work in Uganda and would want to use the multimodal tool after validation in South Africa
- Self report is good; not perfect but useful. Some practitioners are in the forefront of advocating for a more extensive use of the Medication Adherence Self-Report Inventory (MASRI) in the developing countries
- Standardization of adherence measurement tools is a challenge
- The publication “From access to Adherence: the challenges of antiretroviral treatment” produced by WHO, University of Amsterdam and the Royal Tropical Institute, was displayed in a nearby stand. There were discussions across the stands on surveys to identify factors that affect adherence to ART
- There were numerous requests for electronic copy of the reprint

The poster is attached as Annex 1.

Make a presentation on “MSH/RPM Plus experiences and tools for procurement and supply management of AIDS Commodities” during the WHO organized AMDS Satellite of the International AIDS Conference

MSH/RPM Plus was invited by the AIDS Medicines and Diagnostics Services (AMDS) of the WHO to make a presentation on “MSH/RPM Plus experiences and tools for procurement and supply management of AIDS Commodities.” The AMDS Satellite session was held from 10:15 - 12:15 on Sunday August 13th at the conference session room 7. The Satellite session was chaired by Badara Samb of WHO and about 35 people attended including AMDS partners UNFPA, Clinton Foundation HIV/AIDS Initiative, ReMeD France, JSI/DELIVER and the Supply Chain Management System (SCMS). Presentations during the session were restricted to 10 minutes, RPM Plus presentation was abridged to allow for accommodation within the time allowed.

Make a presentation on “MSH RPM Plus experiences in procurement and supply management of AIDS Commodities” at the WHO organized Skills building workshop

MSH/RPM Plus was invited by the AIDS Medicines and Diagnostics Services (AMDS) of the WHO to make a presentation on “MSH RPM Plus experiences in procurement and supply management of AIDS Commodities.” The skills building workshop was held from 11:00 - 12:30 on Wednesday August 16th at the Skills Building room 7. The Skill building workshop was chaired by Peter Graff of WHO and Rich Owens of SCMS. The workshop under theme was on “Solving problems with the procurement of HIV commodities” and had in attendance partners from ESTHER, JSI/DELIVER and the Supply Chain Management System (SCMS) and others. The RPM Plus presentation during the workshop is attached in Annex 2.

Distribute RPM Plus Tools Flyers during the Conference

The AIDS 2006 conference provided an opportunity for the distribution of RPM Plus flyers to both attendees of the WHO AMDS Satellite and the Skills building sessions. About 30 copies each of the following flyers were distributed during the sessions:

1. ITT
2. Dispensing Tool
3. Quantimed
4. IDPIG

Make an oral presentation on “Improving the availability of ARVs in Namibia by streamlining the drug registration process”

RPM Plus/Namibia submitted an abstract which was accepted by the AIDS conference for an oral presentation. The presentation “Improving the availability of ARVs in Namibia by using policy change to streamline the drug registration process” was accepted and scheduled to be part of concurrent panel session entitled: Treatment Access, TRIPS and Trip-ups: Abstract Session. The session was chaired by Gregg Gonsalves (Policy Director of the Treatment Action Group (TAG) and Asia Russell of Health GAP (Global Access Project). The session was held from 16:15 - 17:45 on Thursday, August 17th, Venue: Session Room 4, Level 800. The panelist included Jonathan Berger (AIDS Law Project, South Africa), Gabriella Chaves from Brazil who presented a study exploring the public health sensitivity of intellectual property rights legislation across Latin America, Chan Park of the Lawyers’ Collective in India, the RPM Plus presentation presenter, and Daniel Rosan from the Interfaith Centre on Corporate Responsibility. The session was attended by about 220 conference participants. The majority of the presentations focused on activism to ensure access rather than programmatic issues that can improve obstacles that affect access. The key question directed at the RPM Plus presentation was on if there is a need for the civil society and activist to get involved in ensuring that Pharmaceutical companies register their medicines in developing countries. I provided a response that the drug regulatory authorities, as part of the public health systems in developing countries, can improve the drug registration system to ensure that local requirements for registration do not become an obstacle to access, and that ARVs are registered in a country. The manufacture or the manufacturers

representative/wholesaler/distributor can use the local channels to make those drugs available in their country. The presentation “Improving the Availability of ARVs in Namibia by Using Policy Change to Streamline the Drug Registration Process” is included as Annex 3. A detailed list of all presentations made by Jude Nwokike is listed in Annex 4.

Attend relevant Skills building sessions of the Conference

RPM Plus conducted a Skills building session on using the MTP approach to improve Pharmaceutical management. The session was facilitated by RPM Plus Helen Walkowiak and Lloyd Matowe. I attended the session and assisted in supporting the facilitators with ensuring that participants were following the session.

Attend relevant plenary and sessions of the Conference

I attended the following sessions of the AIDS 2006 conference:

Sessions Attended during the AIDS 2006 Conference	
<u>Theme</u>	<u>Session topic</u>
Time to deliver	Opening ceremony
	Human rights and social vulnerabilities
	From programmes to policies- Now: positive changes for women and girls
HIV testing in the era of treatment scale-up	Routine testing: the Botswana experience - the point of view of the ministry of health
	Expanding HIV testing in developing countries
Maximizing use of community-based health workers and nurses in the provision of HIV-related health care	Presentation on experience with community-based individuals providing care (4 speakers including Paul Farmer)
Prevention: proven approaches and new technologies	Microbicides and other prevention technologies
Responding to the challenges of delivering ARVs in resource-limited settings	Public approach to delivering ARV in resource limited settings
	PMTCT and pediatric issues
HIV and poverty: breaking the vicious cycle	Making money work to benefit people living with HIV/AIDS
Ethical issues in clinical trials	Overcoming the challenges of prevention research: lessons learnt from the tenofovir pre-exposure prophylaxis trials
Advancing treatment and universal access: A report on the state of the art and progress	Re-evaluating the cost-effectiveness of HAART- The case for expanding treatment access to curb the growth of the epidemic
	Children and AIDS
	Prevention and universal access: An issue of sustainability
	From "3 by 5" to universal access
Accountability for implementation of the UNGASS HIV/AIDS Declaration of commitment: Community led monitoring	Panel discussion
The Global AIDS architecture: where do we go from here? The impact of global policies and initiatives on country and local responses to HIV/AIDS	Symposium- Creating the scene for universal access

Money makes a difference: monitoring and accountability of global AIDS funding	Current scientific evidence and programmatic experiences in PMTCT: Scenarios for achieving the global goal of eliminating HIV/AIDS in children
	Country experiences: Successful scaling up approaches, India
Treatment access, TRIPS and Trip-ups	HIV/AIDS and South Africa's war on science
	Measuring public health - sensitive degree of IPR legislation in the context of the WTO TRIPS agreement
	Taking the fight to the realm: The role of patent opposition in the struggle for access to medicines
	Improving the availability of ARVs in Namibia by using policy change to streamline the drug registration process
	Benchmarking research-based pharmaceutical company responses to AIDS, TB, & Malaria
Rapporteur summary session	
Closing session/Plenary session	

Liaise with other MSH attendees during the Conference

The MSH attendees to the AIDS 2006 conference met and decided on the representation of MSH during the conference. MSH staffs at the conference also distributed MSH materials at sessions attended by individual staffs and supported sessions where the MSH presentation was being held by attending those sessions. The MSH staffs attendees' group report can be found in Annex 5.

NEXT STEPS

- Send copies of the presentations made to conference attendees that requested for copies of the respective presentations
- Review the algorithm for the use of adherence measurement tools as contained in the poster on “Analyzing medication adherence measurement tools in predicting ART outcomes in resource-limited settings”
- Maintain communication with others working on adherence to ensure networking and collaboration on current standards

Recommendations

- There is a need to develop a standard and continually updated presentation that captures all RPM Plus tools
- There is a need for the development of an RPM Plus conference package that will have sufficient quantities of flyers
- RPM Plus should collaborate with partners working in the area of adherence to ART
- RPM Plus should focus on strategies for the community delivery of ARV medicines as this seems to be a current challenge

ANNEX 1. POSTER ON ANALYZING MEDICATION ADHERENCE TOOLS IN PREDICTING ART OUTCOMES IN RESOURCE-LIMITED SETTINGS

Analyzing Medication Adherence Measurement Tools in Predicting ART Outcomes in Resource-Limited Settings

J. Nwokike,* G. Steel,* and M. P. Joshi*

*Management Sciences for Health/Rational Pharmaceutical Management Plus (MSH/RPM Plus)

Background

Formally assessing medication adherence in antiretroviral therapy (ART) provides an opportunity to reinforce client behavior or use constructive interventions to address problems. Although various adherence measurement instruments have been validated for accuracy, dependability, and consistency, no systematic review of validated tools applicable to resource-limited settings exists. In this study, Rational Pharmaceutical Management (RPM) Plus Program's objective was to identify validated adherence measurement tools that can be tested on clients undergoing ART in resource-limited settings.

Methods

Search strategy—

- Examine 15 scientific literature databases
- Search for articles published between 1995 and 2005
- Use the following search terms: adherence, adherence measures, assessing adherence, compliance, evaluating adherence, levels of adherence measuring adherence, predicting nonadherence, sensitivity of adherence measures, validity of adherence measures
- Do not consider attributes of measurement such as multidimensional, continuous, and time intervals



Inclusion criteria—

- Validation against an objective measure
- Comparison with objective measure (CD4 or viral load) and/or electronic measures (Medication Event Monitoring System [MEMS])
- Reliability as measured by sensitivity, specificity, and/or positive predictive value
- Studies making reference to dependability, consistency, and reproducibility of results

Note: Studies exclusively using electronic measures were excluded.

Results

- Of the 124 studies found, 57 (46 percent) involved self-reporting. Of the self-reporting studies, 50 (88 percent) confirmed their reliability to predict adherence (Figure 1).
- Of 26 studies on pill counting, 21 (81 percent) confirmed their reliability.
- All five studies using visual analog scale (VAS) were confirmed reliable.
- All 18 studies using a multimodal tool demonstrated their reliability.
- Pill Identification Test, pharmacy refill records, and provider estimate methods had weak sensitivity and low predictive values.

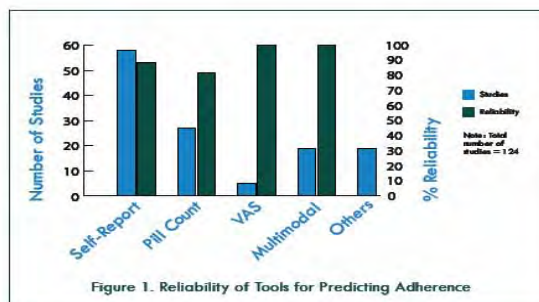


Figure 1. Reliability of Tools for Predicting Adherence

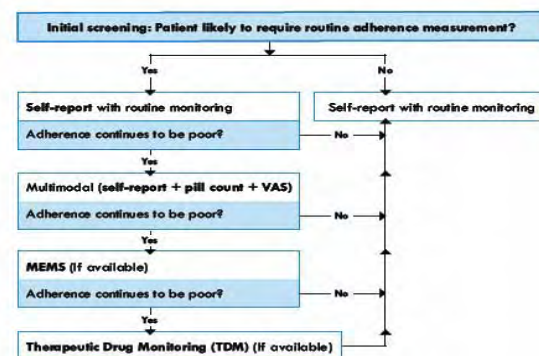


Figure 2. Proposed Algorithm for the Use of Adherence Measurement Tools

Conclusion

ART programs need to reliably monitor client adherence, but validated measurement tools are lacking for resource-limited sites. Based on this analysis, the study identified simple self-report questionnaires, pill counting, and VAS as the best potential adherence measurement tools for resource-limited settings. In settings where these tools have not been tested and calibrated, a multimodal adherence measurement tool is recommended. RPM Plus is using these results to develop a multimodal tool for use in ART clinics in South Africa, with possible applications in other resource-limited settings.

Recommendations for the Applicability of Tools for Resource-Limited Settings

- ART programs must reliably monitor client/patient adherence
- Simple self-reporting, pill counting, and VAS are reliable measurement tools for resource-limited settings
- In settings where these tools have been tested and calibrated, consider using the proposed algorithm (Figure 2).
- In settings where these tools have not been tested and calibrated, a multimodal adherence measurement tool is recommended

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ANNEX 2. MSH RPM PLUS EXPERIENCES IN PROCUREMENT AND SUPPLY MANAGEMENT OF AIDS COMMODITIES

MSH/RPM Plus Experiences and Tools for Procurement and Supply Management of AIDS Commodities

26th International AIDS Conference
Toronto, Canada, August 16, 2006

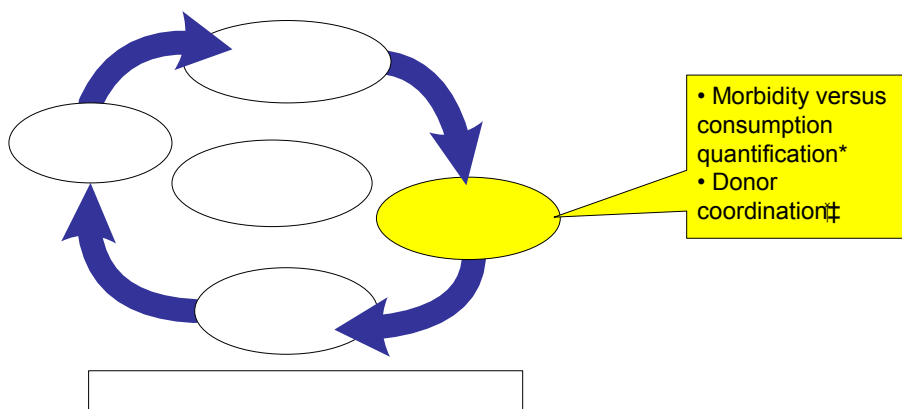


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USAID
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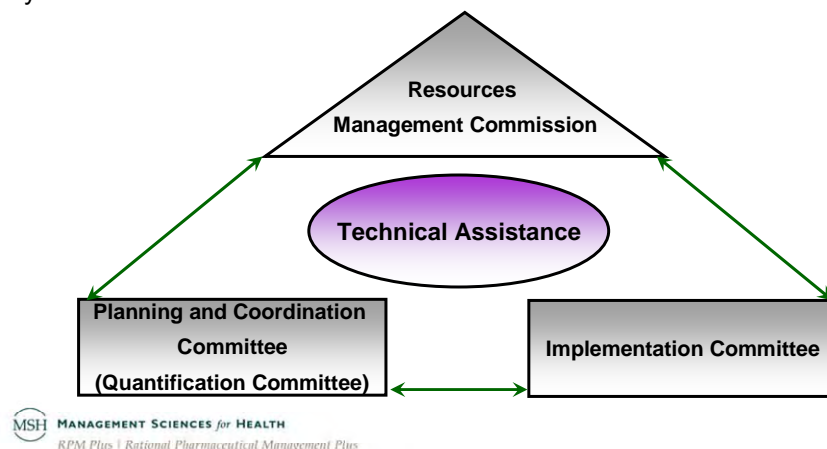
Pharmaceutical Management Cycle



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Experiences with Coordinated Procurement: Rwanda

Coordinated Procurement and Distribution System (CPDS) approved by Government of Rwanda and donors



Experiences with Coordinated Procurement: Kenya

- **National AIDS and STD Control Programme (NAS COP) coordinates procurement**
 - Subcommittees have an advisory role
 - Recommendations of the subcommittees are ratified and forwarded by NAS COP to Ministry of Health (MoH) for implementation
- **Medicines Subcommittee**
 - MoH, donors, facility staff, Kenya Medical Supplies Agency (KEMSA)
 - Responsibilities
 - Determine standard first-line and second-line regimens for antiretroviral therapy (ART)
 - Provide quantification, distribution planning, and quality assurance
 - Support efficient data collection, analysis, and reporting by sites
 - Facility data forwarded to NAS COP to inform decision making
- **Integrated Supply: KEMSA, Mission for Essential Drugs and Supplies (MEDS)**

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Experiences with Coordinated Procurement: Namibia

- **Coordination by the Directorate of Special Programs (DSP)**
 - Meeting of antiretroviral (ARV) committee comprising MoHSS, Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and U.S. Government (USG) to decide level of funding and understand procurement restrictions
 - USG: FDA-approved brand and generic ARVs
 - GFATM: WHO-prequalified generic ARVs
 - MoHSS: Medicines Control Council (MCC) registered/waiver
 - Central Medical Stores (CMS) procures all ARVs and presents invoices to partners through DSP
- **Integrated Supply: CMS**



MSH/RPM Plus Tools—Quantimed

Pharmaceutical Quantification and Cost Estimation Tool

- **Uses**
 - Quantify requirements and calculate estimated cost using four different methods, including the morbidity and consumption methods
 - Determine pharmaceutical requirements for a new or expanding HIV/AIDS program
 - Compare alternative expansion models to inform extent and speed for scaling up
 - Compare the costs of alternative treatment regimens
- **Features**
 - Database with ability to export results to Microsoft Excel
 - Built-in client-adaptable medicines and supply list with median prices from MSH's annual International Drug Price Indicator Guide
 - Comprehensive user's guide
- **Experiences**
 - Quantimed has been used for ARV procurement planning and budgeting for PEPFAR activities in Haiti, Namibia, Rwanda, Kenya, Zambia, Guyana, and the Project for Supply Chain Management (PfSCM)






MSH/RPM Plus Tools—ORION@MSH

Pharmaceutical Management Software for Resource-Limited Settings


- **Uses/Features**
 - Software suite for managing pharmaceuticals and medical supplies in medium-sized hospitals up to national level agencies
 - Six interlinked modules: Accounting, Inventory, Sales and Distribution, Tender and Procurement, Vehicle and Equipment, and Warehouse
- **Experiences**
 - Installed in Dominica, Ghana, Grenada, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, and Tanzania



MSH/RPM Plus Tools— ART Dispensing Tool

- | | |
|--|---|
| <ul style="list-style-type: none">■ Uses<ul style="list-style-type: none">■ Links patient information and individual ART history to stock movement in a facility■ Maintains records for each patient receiving ART<ul style="list-style-type: none">■ Tracks patient profile and medication history■ Generates key management reports, such Monthly Patient Uptake Trends and Currently Active Patients per Regimen■ Generates daily expected patient attendance list to facilitate adherence monitoring | <ul style="list-style-type: none">■ Experiences<ul style="list-style-type: none">■ Cote d'Ivoire: 19 sites■ Haiti: 4 sites■ Kenya: 60+ sites■ Guyana: 9 sites■ Namibia: 4 sites■ Rwanda: 20 sites■ Tanzania: 1 site■ Zambia: 17 sites |
|--|---|





MSH/RPM Plus Tools— ART Inventory Tracking Tool

- **Uses**

- Facilitates management of ARVs, opportunistic infection (OI) medicines, rapid test kits (RTKs), and condoms at an aggregate level, i.e., regional, national
- Tracks expected influx of ARV/OI medicines/RTKs/condoms, estimation of demand disaggregated by month, and number of ART patients by regimen and facility
- Produces reports central to good management of ART such as—
 - Total consumption
 - Total number of patients per regimen
 - Availability of various ART-related pharmaceuticals at facilities

- **Experiences**

- Kenya, Vietnam, Namibia



MSH/RPM Plus Tools— *International Drug Price Indicator Guide*

- Contains prices for over 975 medicines with focus on essential medicines, including ARVs and rapid HIV test kits
- Lists prices paid for medicines by country governments and agencies and prices from international suppliers
- Updated annually
- Lists suppliers and agencies and their addresses
- Produced in collaboration with the World Health Organization since 2000
- Explanatory text and website are in English, French, and Spanish



MSH/RPM Plus Tools—VCT Planning Guide and HIV Test Kits (Information Document)

■ VCT Planning Guide

- Provides practical guidance on VCT commodity management
- Outlines a systemized approach to strengthening VCT
- Contains practical tools and approaches

■ HIV Test Kits (Information Document)

- Developed to assist USAID Missions and CAs in procuring HIV test kits
- Featured HIV test kits are those listed on USAID Source and Origin Waiver (first approved in January 2001)
- Provides detailed information on HIV test kits
- Updated annually or as often as the USAID Source and Origin Waiver is amended

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ANNEX 3. IMPROVING THE AVAILABILITY OF ARVS IN NAMIBIA BY STREAMLINING THE DRUG REGISTRATION PROCESS

Improving the Availability
of ARVs in Namibia by

Streamlining the Drug Registration Process

Dawn Pereko, Jude Nwokike

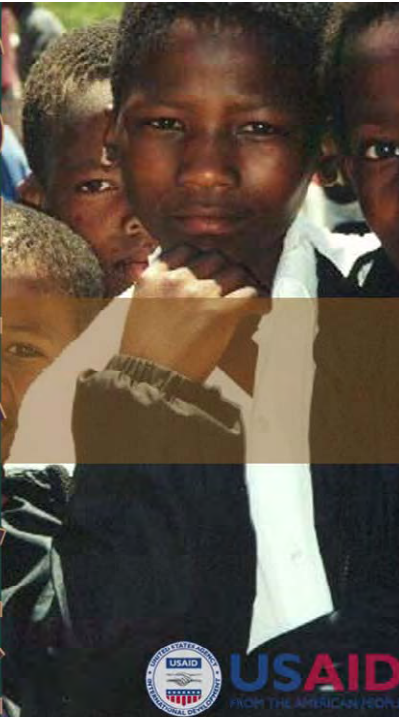
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Background (1)

- In Namibia, the Medicines Control Council (MCC) is the statutory body responsible for registering medicines and ensuring the quality, safety, and efficacy of all medicines in the country.
- Before Namibia's independence on March 21, 1990, the South African MCC registered medicines for both South Africa and Namibia. Even though the MCC in Namibia was established in 1994, medicines registered in South Africa continued to be marketed in Namibia.



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Background (2)

- In 2001, the MCC published a notice regarding the Medicines and Related Substances Control Act of 1965 to call up all medicines marketed in Namibia before 1990. These medicines were deemed to have been registered in Namibia.
- All medicines registered in South Africa after 1990 were considered unregistered, but applicants were given a grace period of six months to market their products, provided they applied for registration
- By March 2004, 2,949 applications for registration had been received, but only 100 applications had been reviewed.



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Background (3)

- In September 2004, thousands of applications were classified as outstanding and in need of review, including—
 - ~ Generic ARVs
 - ~ Fixed-dose combinations (FDCs)
 - ~ Pediatric formulations
- Only 49 branded, generic & single-dose ARVs were on the register
- Because of the backlog, accessing all ARVs was a problem
- Namibia Medicines Register 2005
 - ~ Contains 3888 records
 - ~ South Africa registration: 3,719 products
 - ~ Non-South Africa registration: 169 products



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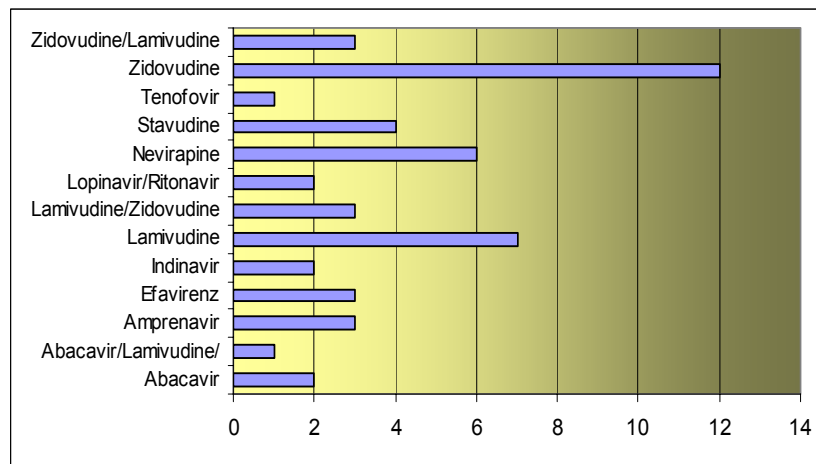
The Unknown Backlog Volume



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Registered ARVs prior to interventions



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Method (1)

- In September 2004 RPM Plus assessed ways to help the MCC clear the backlog of registration application dossiers
- The Pharmaceutical Control and Inspection Sub-division with assistance from RPM Plus worked to—
 - ~ Grandfather certain products marketed in South Africa
 - ~ Approve medicines registered in International Conference on Harmonization member countries
 - ~ Hold Pharmaceutical/Analytical Committee retreats to speed up review process
 - ~ Establish a medicines registration database
 - ~ Develop a database to manage the dossier review process and analyze data.



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Methods (2)

- The MCC Secretariat with support from RPM Plus developed interventions to streamline the registration process by —
 - ~ Prioritizing the review of the ARVs and other essential medicines
 - ~ Establishing a proxy evaluation process to screen products that had already been approved by reputable and competent medicines regulatory authorities recognized by the MCC
 - ~ Holding retreats specifically tailored for the review of ARVs
 - ~ Creating a medicines registration database
 - ~ Training nonprofessional staff on the database



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Method (3)

- Developing a database was recommended to manage the dossier review process and analyze data. Steps used to develop the database included —
 - ~ Determine data elements that need to be captured for decision making
 - ~ Import, merge, and correct data errors in existing spreadsheets
 - ~ Inventory all dossiers received to ensure that all are included in the database
 - ~ Discuss and define the workflow, processes, and information required and incorporate these elements into the registration system



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Method (3) contd.

- ~ Provide and install a local area network and set up backup routines
- ~ Visit the Medicines Control Council of South Africa to become familiar with its computerized registration system and inform decision making
- ~ Finalize the registration database system by confirming the workflow, finalizing software applications, and updating the application documents
- ~ Develop standard operating procedures for the registration process
- ~ Train staff on the use of the new system



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Results

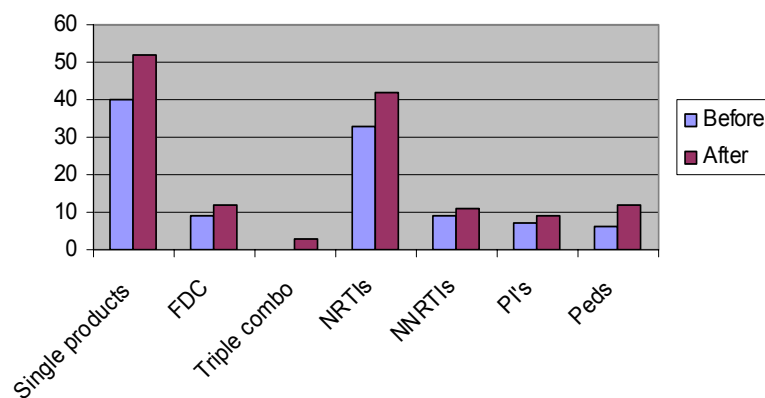
- Intervention measures were put in place in April 2005.
- By February 2006, a total of 1,392 medicines were registered —
 - ~ ARVs in the register increased by 30.6 percent.
 - ~ Fifteen ARVs, including the much-needed FDCs and pediatric formulations, were registered.
 - ~ Twenty-four generic ARVs have been reviewed and when registered will increase the number of ARVs by 75%.



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Increased number of ARVs in the Register post interventions



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Conclusion (1)

- Barriers to accessing ARVs can develop at any level in the pharmaceutical system.
- In Namibia, a combination of policy and managerial interventions streamlined the medicines registration process.



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Conclusion (2)

- Streamlining in Namibia led to improvement in the availability of ARVs for HIV/AIDS treatment.
- During scale-up, countries should monitor and evaluate all aspects their pharmaceutical policies and procedures to find “hidden” obstacles to access.



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ANNEX 4. TORONTO PRESENTATIONS

Toronto itinerary- Jude Nwokike			
Abstract Title	Toronto Status	Author(s)/Country	Date/Location/Time
MSH RPM Plus experiences and tools for procurement and supply management of AIDS Commodities	WHO AMDS Satellite	J. Nwokike	August 13 (Sunday), 10:15 - 12:15
Analyzing medication adherence measurement tools in predicting antiretroviral treatment outcomes in resource-limited settings	Poster	J. Nwokike, G. Steel, M. Joshi	Tuesday 15 August Venue: Poster Exhibition 10:15 - 18:30 (TUPE0129)
MSH RPM Plus experiences in procurement and supply management of AIDS Commodities	Skill building Workshop	J. Nwokike	16 August 2006: 11:00 - 12:30 Location: SBR7
Improving the availability of ARVs in Namibia by using policy change to streamline the drug registration process	Part of concurrent panel session entitled: Treatment Access, TRIPS and Trip-ups. Abstract Session	D. Pereko, J. Nwokike	Thursday 17 August Venue: Session Room 4, Level 800 16:15 - 17:45 (THAE0504)

ANNEX 5. MSH STAFFS GROUP REPORT ON THE AIDS 2006 CONFERENCE

MEMO

To: MSH Worldwide

Date: 28 Aug 06

From: Godfrey Sikipa, Catherine Mundy, Catherine Severo, Sharon Stash, Helena Walkowiak, Sarah Johnson, Erik Schouten, Erin Molloy, Jude Nwokike, Lloyd Matowe

Subject: The Global AIDS Conference, Toronto – Dissemination of MSH’s work, Key messages and their implications for MSH,

Dear Colleagues Worldwide,

MSH was represented at the Global AIDS Conference by ten of us from across MSH and across the world. For some of us, it was the 3rd or 4th conference, for others it was the first. All of us have returned from the Conference full of new information and challenging ideas. This memo will share with you the key messages of the conference and guide you to websites where you can follow up on points that interest you the most.

MSH presentations at the Global AIDS Conference: Several MSH staff members made presentations at the conference through the oral presentations, posters, skills building workshop and satellite symposium. Please see the presentations in the attached MSH briefing document that CKE prepared for MSHers attending the conference. We would like to thank Julie O’Brien, Sherry Cotaco, Erin Molloy, other CKE team members, Amy-Simone, and our travel team for preparing this briefing document and making all the arrangements for MSHers to travel to and interact during the conference.

Key themes and messages at the Global AIDS Conference that will influence MSH’s strategy and approach to HIV/AIDS

- **Key issues in transmission – evolution of the epidemic:** The epidemic continues to evolve at different rates in different parts of the globe. China was applauded for recognizing and addressing its epidemic. The latest “wild” epidemic is in the former Soviet states among Intravenous Drug Users (IDUs) and Eurasia where rates up to 70% are found, mostly among young men. Among Men Having Sex with Men (MSM), incidence may be on the upswing again in both North and South in part as use of condoms declines. Sub-Saharan Africa continues to be the worst affected, with prevalence ranging from 3-7% in East Africa to 19-24% in southern Africa and growing. Incidence among young women and girls is growing fast. Key factors include labor migration, STIs, # of partners, and age at debut.
- **AIDS Vaccine: No progress!** Several dozens of possible vaccine candidates have been developed of which less than a dozen have got to trial. None of them are clinically active. Vaccine development is now organized world wide to create synergy and cost effectiveness. However, the main problem is that the HIV virus attacks the immune system, so vaccine processes that stimulate the immune system don’t seem to work. Furthermore, 75% of all vaccines invented are for acute diseases, while AIDS is more like a chronic disease for which

it is much harder to develop a vaccine. Therefore, key speakers at the conference said that it may take another ten years or more to develop one.

Development of vaginal microbicides: Trials underway, some trials in late stages, results will become available in 2007-08. Two types of microbicides are under development: one type is a straightforward microbicide that can be combined with contraceptives, the other type actually contains anti-retroviral drugs. These products would present as a gel, be used with a cervical diaphragm, or be slow released through a cervical ring. Most importantly, they would give women control over prevention. Bill Gates among others said that not nearly enough is being done to develop new prevention tools. Melinda Gates said: "Today, fewer than one in five people at greatest risk of HIV have access to proven approaches like condoms, clean needles, education and testing." If vaginal microbicides become available in 2008, prevention approaches will shift back towards reproductive health and family planning linked activities.

IMPLICATIONS FOR MSH . We should track this work closely and be prepared to support introduction of vaginal microbicides in centers and through community distribution approaches.

- **Male circumcision:** Circumcision is becoming an important strategy to reduce or prevent the transmission of HIV/AIDS. The main issues coming Conference were: (1) Studies have indicated that circumcision can result in as much 60% reduction in HIV transmission in males; (2) WHO and UNAIDS are currently monitoring the results of two clinical trials that are being conducted in Uganda and Kenya before deciding and issuing policies and guidelines to countries; (3) Demand for circumcision as a way to reduce STI and HIV transmission is already rising in some countries where circumcision was not previously widely practiced. There are important operational issues that need to be addressed in popularizing circumcision, safely performing the operation and providing the requisite post op and follow-up care on a large scale. In one of his speeches, Bill Clinton noted that if these results are true, the challenge will be to develop an approach to adult male circumcision that is clinically safe, cost effective, and socially acceptable. No one believes this will be easy!

IMPLICATIONS FOR MSH We are well placed to make a significant contribution in the international effort to make circumcision accessible to all who need it. MSH experience with introducing vasectomy should be useful here.

- **Treatment of pediatric AIDS with HAART and Cotrimoxizole prophylaxis:** An estimated 2.3 million children are HIV+ of whom 300- 660,000 need HAART. Untreated mortality rates are 21% by 6 months of age, 37% at 12 months, 52% at 2 years, 60% at 6 years. Definitive evidence from clinical trials was presented showing the effectiveness of HAART for children (80-84% survival in treated groups with 5% > CD4 > 15%) – even children who were profoundly immunosuppressed benefited from ART. After 1 year of treatment, up to 83% of children had attained a CD4 > 25% (= target). HAART is well supported by children, only 15% require a change of therapy due to co-infection by TB or side effects. Studies showed 87% full compliance with treatment in developing countries. The under-representation of younger children (less than 2 years) was highlighted in all the presentations – in Zambia presentation, the average age for starting ART was 8 years; in

Brazil there are big regional differences in age of diagnosis, in MSF programs 4.7% of children starting ART were aged 0-17 months. Cotrimoxazole prophylaxis increases survival by 43% and may be needed by about 2 million children 0-14 years old to prevent opportunistic infections. Therefore, **all countries should adopt free access to HAART for children using the WHO guidelines & nutrition support.** Simpler presentations and combined dose forms are needed. New testing techniques are in final stages of development using a centralized laboratory process

IMPLICATIONS FOR MSH: introduction of new testing techniques means more work for Mundy, et al.! Remember to include pediatric aids approaches, including lab strengthening, in strategic plans and drug procurement forecasts and guidelines,). Adapting pharmaceutical management tools developed for adult programs is a priority to support scale up – possible now that many questions are being answered.

- **PMTCT:** PMTCT using nevirapine alone can reduce transmission by 67% while combined therapies reach 95%. WHO guidelines on PMTCT have been launched, including prolonged treatment of the mother. Survival of the mother increases child survival by 50%, justifying the PMTCT Plus strategy. Currently PMTCT interventions are reaching less than 10% of the women worldwide who could benefit. Need to integrate PMTCT and ART treatment programs earlier to implement more comprehensive interventions – engage women and families in ART treatment earlier, identify infants infected with HIV earlier, follow up with siblings. Some models discussed include (1) refer women from ANC to ART clinic; (2) mobile ART team visits ANC clinic (MSF)

IMPLICATIONS FOR MSH: Verticalization of PMTCT programs unlikely to continue – MSH well placed to help countries address the management issues of integrating PMTCT supply into existing programs – supply and dispensing of PMTCT regimens; organizing systems to link PMTCT programs with pediatric ART, adult ART

- **Harm reduction approaches:** Harm reduction aims at reducing transmission of diseases and mortality from intravenous drug use. Harm reduction approaches include needle exchange, safe injection sites (such as drop in centers), substitution therapy, condom distribution, etc. In general, these approaches make governments and main stream citizens very nervous; few countries have tried more than pilot projects. However, evidence from Canada and Brazil were presented to show that HR reduces mortality among IDUs without increasing drug related crime. Brazilian data showed decreased prevalence of AIDS among IDUs after introduction of HR and free access to ART from 1996 (63% in Baixada state) to 2000 (42%). Harm reduction also prevents hepatitis B & C.

IMPLICATIONS FOR MSH: We need to help countries begin thinking about and piloting harm reduction approaches in accordance with national policies and currently available best practices.

- **ABC approach:** The AB and ABC approaches came in for almost universal bashing during the conference. While there is recognition that abstinence and faithfulness in relationships have their role in prevention of the transmission of HIV and other STIs, many speakers spoke

very strongly about the need for reality and thus make condoms more available and the need for investment in other prevention strategies such as harm reduction and targeted education and information dissemination.

- **Opt-out testing vs. VCT:** Debate continues to rage on the most appropriate approach to testing. Human rights activists deplore opt-out testing strategies while others are frustrated with low enrollments and slow scale up of HAART. No good studies or models of the effectiveness of opt-out were presented nor were any new approaches to scaling up demand shown.
- **Improving access to HIV testing** – Uganda's home-based HIV VCT program was presented as a new model for improving access to VCT where most of the population is in rural communities. Parish mobilizers work with the community to determine demand for testing and then the counselor and laboratory assistant come to the home for VCT. In all developing country presentations, the problems with availability of HIV test kits came up repeatedly.
- **IMPLICATIONS FOR MSH:** Implications of this new model for supply management, training, human resources, supervision – integrate considerations into our existing approaches. Consider including activities to strengthen commodity management to support HIV testing in workplans.
- **Free access to treatment:** Definitive clinical evidence was presented that free access to ART treatment improves survival. Among results presented, a study from Taiwan showed a 53% decrease in incidence after introduction of free access to HAART. This study used incidence of syphilis as a control marker for STI incidence. (Lancet, 2006, 368: 531-536 & JID, 2004: 190 (1 Sept), 879). Free access to treatment is therefore more **than a social equity issue, it is a prevention strategy.**
- **The Bills:** Bill Gates and Bill Clinton, both recognized figures in the fight against HIV and AIDS, mentioned the following important current priorities: prevention activities that go beyond abstinence, wider treatment access, fighting stigma to increase testing, wider issues of poverty and hunger.

IMPLICATIONS FOR MSH: Unless there is consistent availability and access of test kits, drugs and other commodities at the point of service (hospitals, health centers, communities and homes), treatment is unlikely to become any much wider than the current levels. The availability of drugs and commodities at all these levels is very much dependent on the leadership, general planning and management capabilities of health workers as well as their skills to forecast, order, use and monitor commodities efficiently and effectively. These are all areas in which MSH is a known and recognized world-wide leader. We therefore need to strategize over the next few months on how we can make avail our wealth of experience and skills in these areas in order to make Universal Access of treatment a reality.

- **Clinical mentoring and training:** Many of the skills building workshops and some satellites addressed training and there were several sessions on clinical mentoring for medical staff and also nurses, pharmacy staff and others. There was much discussion on the management

issues around clinical mentoring – supervision of both the mentor and those mentored; selecting appropriate clinical mentors; different models of mentoring and successes and failures. There was also interest in moving towards best practices in terms of training – in terms of materials and methods.

IMPLICATIONS FOR MSH: Timing is good to publicize and disseminate MSH's existing HIV/AIDS training materials especially for commodity management and also to move forward with an MTP approach as an increasing number of academic institutions move forward with clinical mentoring programs.

- **Some missing themes/issues:** While each GAC focuses on a specific set of issues, this conference seems to have certain blind spots - issues that have been crucial in earlier years but somehow rather absent this time. We noted limited attention paid to condom promotion as linked to other activities (such as harm reduction), systems strengthening as a priority, AIDS and reproductive health. Although there was considerable discussion of the total amount of money available for AIDS work and a new catchy slogan "Fund the Gap" for the Global Fund, very little attention was given to the mechanics of using funds effectively, approaches, lessons on how to scale up national and regional programs and implement multi-sectoral partnerships. There was no report on how much of all the new money actually got spent See: www.the-lancet.com Vol 368 August 26,2006. A prescription for AIDS 2006-10.
- **Skills building workshops:** At this conference MSH organized one and participated in 2 other skills building workshops. We found that this was an effective mechanism to disseminate the kind of work we do in strengthening management systems – to engage participants, build management skills and then provide useful tools. We learnt that advertising the event is really important – on discussion groups before the conference and distributing flyers – to reach the relatively few pharmaceutical management people who attend. But the people who came really engaged and reported back favorably.

For more information on the results presented at the conference please see:

- www.aidsmap.com/en/news
- The Lancet, Vol. 368, Number 9534, August 5-11, 2006. Entire number devoted to AIDS results. Also available on The Lancet website at www.thelancet.com.
- www.kaisernetwork.org/aids2006/

A note about an MSH booth: MSH did not have a booth to display MSH products/documents at this conference. This was not for lack of trying. Space was in short supply and the conference organizers closed applications for booths quite early. It is important that in future we book space for a booth early. MSH has a lot of products to show case. For future conferences we need a budget for communications to enable MSH to display its documents and contributions in the fight against HIV/AIDS.

MSH meeting at the Conference: Taking the cue from MSHers who attended the PEPFAR Durban Conference, MSHers attending the 16th Global Conference had a formal meeting to

discuss coordination of HIV/AIDS programming in MSH. The time that we had allocated for the meeting proved to be grossly inadequate. So we met again over dinner during we had the opportunity to brainstorm again on how best MSH can coordinate the many excellent contributions that we are making to the international effort against HIV/AIDS. The main points to come out of the meeting are:

1. We need within MSH, a forum or mechanism for people from various centers and offices to meet regularly on HIV/AIDS issues. The forum should be largely composed of “operational level;” staff members and field staff. Experience with the current HIV/AIDS Team is that the current members are very busy senior managers.
2. In order to allow for meaningful good quality interactions on HIV/AIDS between field staff and HQ, MSH should organize a day-long meeting during the Global AIDS Conferences and the Regional AIDS Conferences such as ICASA (to be held a day before the beginning of the main meeting). Such an approach would keep costs low because some of the field staff would be funded through projects.

In order for us not to lose momentum and the enthusiasm of MSH staff in the field and home office to strengthen MSH’s work in HIV/AIDS and improve coordination, please send ideas, comments and suggestions for follow-up to Godfrey Sikipa. In the next few weeks we hope to initiate/revive an MSH e-forum for HIV/AIDS.